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| 10/729,114 | 12/05/2003 | Scott A. Burton | 59098US002 | 3162 |

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| EXAMINER | |
|---|---|
| GHALI, ISIS A D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1611 | |

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|---|---|
| 12/15/2008 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
LegalDocketing@mmm.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/729,114 | BURTON ET AL. | |
| | Examiner | Art Unit | |
| | Isis A. Ghali | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/09/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The receipt is acknowledged of applicants' amendment, request for RCE, and IDS, all filed 09/09/2008.

Claims 1-25 previously presented, claims 26-28 have been added by applicants' amendment filed 09/09/2008.

Claims 1-28 are pending and included in the prosecution.

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/09/2008 has been entered.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The new claims 26 and 28 added new matter. Claim 26 recites: "wherein the wound dressing is swollen with a liquid" and claim 28 recites: "swelling the wound dressing with liquid". Nowhere applicants disclosed wound dressing swollen with liquid. Applicants refer to page 4, lines 18-24 for support. In page 4, lines 18-24, applicants disclosed that: "Wound dressings containing such compositions of the present invention can be used in their hydrated or swollen forms if desired. However, because the wound dressings include an apertured, liquid permeable substrate, the construction is prepared in such a way that the polymer composition can absorb fluid, yet in the swollen state, the apertures are not swollen shut. This allows fluid to traverse the dressing (perhaps into an overlying sorbent material, such as gauze) and not get trapped under it." Therefore, no disclosure that the wound dressing is swollen with liquid. Applicants disclosed that the polymer composition can be hydrated or swollen, but did not disclose wound dressing is swollen with liquid.

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-73 of copending Application No. 10/728,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common subject matter as follows: wound dressing comprising organic polymeric matrix and hydrophilic microparticles. The difference between the present claims and the conflicting claims is that the present claims recite substrate. The substrate is known in the art of

wound dressing, and one having ordinary skill in the art would have provided substrate to support the polymer matrix. The present claims and the conflicting claims of the copending application are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. The examiner acknowledged applicant's intention to provide an appropriate response to the double patenting rejection upon an indication of otherwise allowable subject matter and in the event this rejection is maintained. However, "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-8, 13-18, 21, and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '087.

The present claim 1 is directed to composition comprising hydrophobic organic polymer matrix, hydrophilic organic microparticles, and optionally plasticizer.

WO '087 teaches medical article comprising an adhesive composition comprising a polymeric matrix and absorbent particles of microcolloid (abstract; page 3, 7th paragraph; page 7, 1st paragraph; page 11, 3rd paragraph; page 12), and preferably the particle size less than 1 micron (page 4). The microcolloid particles form from 5-100% by weight of the adhesive composition (page 5, 3rd paragraph). The adhesive composition further comprises a plasticizer (page 14, 3rd paragraph; page 18, 2nd paragraph). The particles are dry powder, i.e. nonhydrated (page 5, last paragraph). The microcolloid particles of the composition delivered in a carrier liquid in the form of a suspension, as required by claim 13, and also on claims 26 and 28 that require liquid (page 6, 1st paragraph; page 12, 9th paragraph). The particles are made of acrylic acid polymer (page 15, 1st paragraph; page 16, 4th paragraph). The polymeric matrix is

preferably hydrophobic (page 6, 6th paragraph). The polymer matrix comprises S-EB-S as claimed by claim 25 (polystyrene-polyethylene/butylene-polystyrene), S-I-S and S-B-S copolymers (page 17, 5th paragraph). The polymer matrix may contain combination of polymers (page 17, 3rd paragraph; page 18, 3rd paragraph). The adhesive composition is coated on porous substrate to form wound dressing that absorbs wound exudates (page 9, 2nd and 3rd paragraphs). The adhesive matrix further comprises active agents including antibacterial agents (page 19, 3rd paragraph).

Although WO '087 teaches polymer matrix having the same ingredients as instantly claimed, however, the reference does not explicitly teach that the composition displays the peel strength from stainless steel as instantly claimed by claims 1, 19 and 20. However, those of ordinary skill in the art would have been readily optimized effective amount of each ingredient as determined by desired properties and intended use of the composition and site of application of the wound dressing. Determination of the appropriate amounts involving each of the above mentioned ingredients would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed prior art.

While WO '087 teaches fine pore sizes of the porous substrate, it does not explicitly teach pore size of 1 mm to 0.5 cm as claimed by claim 8 or the number of the pores per square cm as claimed by claim 7. It is the examiner's position that the pore size and their number are result effective variables because changing them will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that

"discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in WO '087 in page 10, 1st paragraph, where the reference teaches that porosity can be controlled and higher porosity is advantageous.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to adjust the amount of different ingredients of the composition disclosed by WO '087 to achieve the desired degree of adhesiveness of the composition, and to utilize appropriate pore sizes and numbers of pores of the substrate/square unite, including those within the scope of the present claims, so as to produce desired end results of moisture absorption and thereby arrive at the presently cited claims.

10. Claims 9-11, 19, 20, 22, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '087 in view of the article "SALCARE® SC95" by Ciba®.

The teachings of WO '087 are previously discussed as set forth in this office action.

Although WO '087 teaches varieties of materials of the microcolloidal particles including acrylic polymers, however, the reference does not specifically teach the specific material of the microparticles as claimed by claims 9-11, 19, 20, 22, and 23.

The article teaches that "SALCARE® SC95" is a cationic homopolymer dispersed in medicinal grade white oil. SALCARE® SC95 does not require pre-mixing or special

equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical article comprising an adhesive composition comprising a hydrophobic polymeric matrix and absorbent particles of acrylic acid polymers as disclosed by WO '087, and replace the acrylic acid particles by SALCARE® SC95 particles disclosed by the article of Ciba®. One would have been motivated to do so because of the article of Ciba® teaches that such material does not require pre-mixing or special equipment, has high thickening efficiency, and gives good uniform performance when incorporated in cosmetics. One would have reasonably expected formulating medical article comprising an adhesive composition comprising a hydrophobic polymeric matrix and absorbent particles made of SALCARE® SC95 that is safe to the skin and easy to produce.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '087 in view of US 4,902,565 ('565).

The teachings of WO '087 are previously discussed as set forth in this office action.

Although WO '087 teaches varieties of materials of the microcolloidal particles including acrylic polymers, however, the reference does not specifically teach the specific material of the microparticles as claimed by claim 12.

US '565 teaches wound dressings having porous substrate that is preferably a foamed plastics material having interconnecting cells and advantageously having a fine pore size to provide greatest surface area and fastest water uptake (col.3, lines 6-15). The substrate comprises solid water absorbing particles that are preferably finely powdered, having high water absorbing and retaining properties. Examples of suitable polymer materials are polymers or copolymers of acrylamide or polymers of one or more acrylic monomers with acrylic or methacrylic acid. When unsaturated acid monomers are employed, the acid groups may be neutralized by treatment with an alkali metal hydroxide, such as sodium hydroxide, which reads on the copolymer of claim 12. Preferably, the particulate, water-absorbing material has a particle size of less than 50 microns (col.2, lines 1-21).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical article comprising an adhesive composition comprising a hydrophobic polymeric matrix and absorbent particles of acrylic acid polymers as disclosed by WO '087, and replace the acrylic acid particles by particles comprising copolymer of acrylate salt and acrylic acid as disclosed by US '565. One would have been motivated to do so because US '565 teaches that such particles have high water absorbing and retaining properties. One would reasonably expected formulating medical article comprising an adhesive composition comprising a hydrophobic polymeric matrix and absorbent particles of copolymer of acrylate salt and acrylic acid that has high water absorption capacity and retaining properties that are advantageous to the wound dressing and wound healing.

***Response to Arguments***

12. Applicant's arguments filed 09/09/2008 have been fully considered but they are not persuasive. Applicants argue that WO '087 is not directed to non-adherent composition, but adhesive. Applicants further argue that the reference teaches peel strength of $90^0$ from steel.

In response to this argument, it is argued that the present claim is directed to a product, and all the elements of the product are taught by the WO '087. The adhesive properties of the product disclosed by WO '087 is provides by adhesive material added to the polymer composition. It has been held that "Omission of an Element and its function is obvious if the function of the element is not desired." *Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). Therefore, one having ordinary skill in the art would have prepared the polymer composition disclosed by WO '087, and eliminate the adhesive if not desired.

Regarding the peel strength disclosed by the reference, it is argued that the peel strength disclosed by WO '087 is that of the adhesive composition itself and not that of the whole product, while the peel strength disclosed and claimed by the instant invention is that of the product including the polymer composition and the permeable apertured substrate. Hence, comparing the peel strength of the polymer composition by itself and the instantly claimed product is uneven comparison.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

IG